

Message Text

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PAGE 01 STATE 178164
ORIGIN HEW-06

INFO OCT-01 AF-10 EUR-12 EA-12 NEA-10 ISO-00 OES-09
SIG-03 MMO-01 PA-02 EB-08 /074 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO

APPROVED BY OES/ENP/EN: WJWALSH, III

DHEW/PHS/OASH/OIH: REVANS

NEA/IRN:MGREENE(INFO)

EUR/NE:RWOODS(INFO)

EUR/CE SKLINGAMAN(INFO)

EUR/NE:SWORREL(INFO)

EUR/WE:JDOBBINS(INFO)

EUR/NE CSCHALLER(INFO)

NEA/ARP:FGERLACH(INFO)

EUR/WE:AHUGHES (INFO)

EUR/CE:JHURLEY JR (INFO)

AF/S:JTAYLOR (INFO)

EA/ANP:WGALLAGHER (INFO)

EUR/WE:KSMITH (INFO)

EUR/NE:DDONCHI (INFO)

EUR/WE:BMCKINLEY (INFO)

EUR/NE:WNEWLIN (INFO)

EA/J:EFEATHERSTONE (INFO)

EA/ANP:TWAJDA (INFO)

-----035247 150335Z /20

P 142057Z JUL 78

FM SECSTATE WASHDC

TO AMEMBASSY TEHRAN PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMEMBASSY BONN PRIORITY

AMEMBASSY LONDON PRIORITY

AMEMBASSY PARIS PRIORITY

AMEMBASSY COPENHAGEN PRIORITY

AMEMBASSY JIDDA PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY BRUSSELS PRIORITY

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AMEMBASSY BERN PRIORITY

AMEMBASSY PRETORIA PRIORITY

AMEMBASSY WELLINGTON PRIORITY

AMEMBASSY VIENNA PRIORITY

AMEMBASSY LISBON PRIORITY

AMEMBASSY OSLO PRIORITY

AMEMBASSY HELSINKI PRIORITY

AMEMBASSY ROME PRIORITY
AMEMBASSY THE HAGUE PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY CANBERRA PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, IR, SW, GW, UK, FR, DA, SA,
SP, BE, SZ, SF, NZ, AU, PO, NO, FI, IT, NL, JA, AS

SUBJECT: FDA ADVISORY - POSSIBLE FLOW RATE ERRORS IN VOLUME
PUMPS (RECALL T-124-8)

1. FDA ADVISES OF THE FOWING FCM INITIATED RECALL:
PRODUCT INVOLVED - THE PRODUCTS INVOLVED IN THIS RECALL ARE
IVAC VOLUME PUMPS, MODELS 600 AND 60,. THE PRODUCTS ARE
USED FOR INTRAVENOUS INFUSION OF LIQUIDS.

2. PRODUCT IDENTIFICATION - THPRODUCT LABELING CONSISTS
OF SEVERAL SEPARATE LABELS ATTACHED AT VARIOUS POINTS ON
THE MACHINES. THESE VARIOUS LABELS READ IN PART AS FOLLOWS:
"VOLUME PUMP..." "MODEL... VOLTS..." ,START-UP PROCEDURES..."
"CLOSE I.V. TUBING CLAMP BEFORE OPENING DOOR..." THE MODEL
600 IS THE FOREIGN MODEL OPERATING AT 220 VOLTS. A USER
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INFORMATION BROCHURE ACCOMPANIES THE PRODUCTS. ALL SERIAL
NUMBERS OF THE DEVICES ARE INVOLVED.

3. MANUFACTURER/RECALLING FIRM: IVAC CORPORATION,11353
SORRENTO VALLEY ROAD, SAN DIEGO, CALIFORNIA.

4. REASON FOR RECALL - A POSSIBILITY EXISTS
VARIATIONS IN FLOW RATE FROM THE SET VALUE. THE MACHINE
IS USED WITH DISPOSABLE CARTRIDGES OF LIQUIDS WHICH MAY
SPILL LIQUID ONTO THE MACHINE IF CARE IS NOT TAKEN IN
REMOVING THE CARTRIDGES FROM THE MACHINE ACCORDING TO
THE DIRECTIONS IN THE USER INFORMATION PAMPHLET. THE
LIQUID MAY CONTACT THE THUMBWHEEL SWITCH, FLOWING INSIDE.
THE PRESENCE OF FLUID AMONG THE TRACES
ON THE CIRCUIT BOARD OF THE MACHINE MAY CREATE NEW
PATTERNS REPRESENTING DIFFERENT INFUSION RATES THAN THAT
SET ON THE MACHINE. NO DEATHS HAVE BEEN REPORTED IN
CONNECTION WITH THIS PROBLEM. TWO COMPLAINTS HAVE BEEN
RECEIVED, HOWEVER, WHERE OVERINFUSION RESULTED IN
PATIENT AGITATION AND RESPIRATORY PROBLEMS. THE PATIENTS
RECOVERED, HOWEVER, WITH NO FURTHER PROBLEMS.

5. POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY HAVE BEEN ADVISED OF THE PROBLEM BY FIRM AND ITS RESOLUTION. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING RECALL SHOULD BE DIRECTED TO FIRM.

6. FOREIGN CONSIGNEES AS PROVIDED TO FDA BY FIRM ARE:

ADVANCE MEDICAL LTD., SHAH ABBAS AVENUE, 20TH STREET NR 61,
TEHRAN 15, IRAN

AGA-SWEDEN, S-181 81 LIDINGO, STOCKHOLM, SWEDEN

AGA-GERMENY, P.O. BOX 620107, TARPAN 15, D 2000 HAMBURG 62,
WEST GERMANY WG
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BOC MEDISHEILD LTD., ELIZABETH WAY, HARLOW, CM 195 AB
ESSEX, ENGLAND

CRPO, C/O LENORMAND, ORLY OR DEGAULLE AIRPORT-PARI,
DELIVER G RUE HELENE LOIRET, MEUDON, FRANCE 00092

DAMECA A/S, SCHRAMM TRADING APS, ISLEVDALVEJ 211,
DENMARK-2610 RODOURE, COPENHAGEN, DENMARK

DELHOMME R AND COMPANY, 32 AVE DE ST MANDE, PARIS FR
CE

KING ABDUL AZIZ UNIV HOSPITAL, P.O. BOX 245, RIYADH,
KINGDOM OF SAUDI ARABIA, SAUDI ARABIA

GUIDO RAYOS X.S.A., APARTADO DE CORREOS, 4110, MADRID 4,
SPAIN

IVAC UK, IVAC HOUSE, 98/100 BESSBOROUGH ROAD, ARROW,
MIDDX, HA1 3 DT, ENGLAND

S.A. LABAZ N.V., S.F.T. GONDRAND FRERES, RUE DU CHANTIER,
2 B-1000 BRUSSELS, BELGIUM

LAUBSCHER AND COMPANY LTD., RHEINSPRUNG P.9. BOX CH-4001,
BASEL, SWITZERLAND

MARCUS FREDRECK C AND CO., TD., P.O. BOX 3039 7TH FLOOR,
CAPE TOWN, SOUTH AFRICA

MEDICAL SUPPLIES, 79 CARLTON GORE ROAD, P.O. BOX 1234,
AUCKLAND, NEW ZEALAND
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MEDPLAN GMBH VIENNA, TRAPPELGASSE 8, A-1040 VIENNA,
AUSTRIA

MUNDINTER, AV ANT AUG AGUIAR 138, APARTADO 2761 LISBON,
PORTUGAL

NORGAS A/S, SANDAKERVN 64 OSLO 4, NORWAY

OY AGA AB, SF-02610 ESPOO 61, HLSINKI, FINLAND

PIERREL S.P.A., DIV SOXIL, VIA ANTONELLI 3, MILAN, ITALY

STOPLER INSTRUMENTEN, ST LAURENSDREEF 22, P.O.BOX 2445,
UTRECHT, HOLLAND

TOP SURGICAL MFG., CO. LTD., 4-6 SENJI TATUTA-CHO,
ADACHI, TOKYO 120, JAPAN

ULSTER ANAESTHETICS LTD., 340 RAVENHILL RD., BELFAST,
NORTH IRELAND

WATSON VICTOR LTD., 95-99 EPPING RD., NORTH RYPE, AUSTRALIA

WATSON VICTOR, 4 ADELAIDE ST., WELLINGTON, NEW ZEALAND

VIA LENORMAND, ORLY OR DEGAULLE AIRPORTS - PARIS, FOR
ULTIMATE DESTINATION: CFPO 6 RUE HELENE LOITET, MEUDON,
FRANCE 00092. CHRISTOPHER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RECALLS, PUMPS
Control Number: n/a
Copy: SINGLE
Draft Date: 14 jul 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE178164
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780290-0287
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780758/aaaabwxi.tel
Line Count: 204
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: f2e20773-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2001412
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - POSSIBLE FLOW RATE ERRORS IN VOLUME PUMPS (RECALL T-124-8)
TAGS: OGEN, ETRD, EIND, TBIO, IR, SW, GE, UK, FR, DA, SA, XX
To: TEHRAN STOCKHOLM MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/f2e20773-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014